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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/083,849	10/19/2001	Mathieu Hubertus Maria Noteborn	2906-4996.1US	4522

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EXAMINER

MCKELVEY, TERRY ALAN

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 01/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/083,849

**Applicant(s)**

NOTEBORN ET AL.

**Examiner**

Terry A. McKelvey

**Art Unit**

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-12, 14-18 and 20-25 is/are pending in the application.
- 4a) Of the above claim(s) 1-4, 8-12, 14-18 and 20-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 5-7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 October 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 10/19/01.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

Art Unit: 1636

#### DETAILED ACTION

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. §§ 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 because this application fails to provide a properly signed statement indicating that the CRF disk and the paper sequence listing are the same and include no new matter.

In the instant case, a statement was electronically filed 5/5/03. However, it was not properly signed because the electronic signature lacks the required forward slash immediately after the name in the signature.

Applicants are required to comply with all of the requirements of 37 C.F.R. §§ 1.821 through 1.825. Any response to this Office Action which fails to meet all of these requirements will be considered non-responsive. The nature of the noncompliance with the requirements of 37 C.F.R. §§ 1.821 through 1.825 did not preclude the continued examination of the application on the merits, the results of which are communicated below.

Art Unit: 1636

***Election/Restrictions***

Applicant's election without traverse of Group II, claims 5-7 in the reply filed on 11/1/04 is acknowledged.

Claims 1-4, 8-12, 14-18, and 20-25 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11/1/04.

***Oath/Declaration***

It appears that an oath/declaration has been submitted. However, the oath/declaration was not properly scanned and entered into the instant application file and thus could not be reviewed. A copy of the oath/declaration is required in response to the instant Office Action.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Art Unit: 1636

Claims 5-7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a vector which further comprises a nucleic acid molecule encoding a kinase capable of phosphorylating Apoptin or functional equivalent and/or functional fragment thereof. Thus, the claims are drawn to a genus of compounds (any nucleic acid molecule encoding any kinase having the recited activity) that is defined only by their function.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In the instant case, the only thing present in the claims and the specification is that the claimed

Art Unit: 1636

vector comprises a nucleic acid molecule encoding a kinase that is defined only by the activity of phosphorylation, which is not a description of the actual structure of the kinase or the nucleic acid molecule encoding the kinase. It is well established that in the absence of a correlation between specific protein structure and specific protein function, the structure of a protein having a particular function cannot be determined from the activity of the protein. The specification fails to describe the specific structure of even one kinase or nucleic acid encoding the kinase having the specific kinase activity as claimed. Except for showing that a tumor-specific kinase of Apoptin generally exists in tumor cells, a nucleic acid molecule encoding the kinase having the activity as claimed is not described in any fashion in the application.

Accordingly, in the absence of sufficient recitation of distinguishing characteristics, the specification does not provide adequate written description of the claimed vector comprising a nucleic acid encoding a kinase capable of phosphorylating Apoptin.

*Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of

Art Unit: 1636

the 'written description' inquiry, *whatever is now claimed.*"

(See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is now is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of vectors drawn to a genus of nucleic acid molecules encoding a kinase which phosphorylates Apoptin, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation or identification. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, the claims fails to meet the written description provision of 35 U.S.C. 112, first paragraph. Applicant is

Art Unit: 1636

reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1115).

Claims 5-7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Enablement is considered in view of the *Wands* factors (MPEP 2164.01(a)). These include: nature of the invention, the state of the prior art, the predictability or lack thereof in the art, the amount of direction or guidance present, the presence or absence of working examples, the quantity of experimentation necessary, the relative skill levels of those in the art, and the breadth of the claim. The most relevant *Wands* factors for evaluating the enablement of the instant rejection are discussed below.

The claims are drawn to a vector which further comprises a nucleic acid molecule encoding a kinase capable of phosphorylating Apoptin or functional equivalent and/or functional fragment thereof.



Art Unit: 1636

The nature of the invention is unpredictable because the specification does not set forth a description of the kinase having the activity as claimed or a nucleic acid encoding the kinase, for the reasons described above.

The state of the prior art and predictability in the art is that the structure of a protein having a specific activity that is not known in the prior art, a kinase that is capable of phosphorylating Apoptin in the instant case, is not predictable from the function. Instead, the structure of the protein having a previously unknown function must be determined empirically (usually by isolation and sequence determination of the protein and/or nucleic acid encoding the protein) for any given protein or protein system because protein structures are not predictable from a function or activity of the protein in the absence of additional information. That additional information is not taught in the specification and the prior art cannot be relied upon because the protein and protein's activity is not taught in the prior art.

There are no working examples of a vector comprising a nucleic acid molecule encoding a kinase having the claimed activity in either the specification or the prior art.

Beyond showing that the kinase is present in some tumor cells and has the activity of phosphorylating Apoptin, there is

Art Unit: 1636

no guidance concerning the kinase. There is no guidance as to how to specifically isolate the kinase, or whether there is only one kinase or more than one kinase. There is also no guidance concerning the structure of the kinase(s) at all.

Therefore, in order to make the claimed invention, which is also needed for using the claimed invention, one skilled in the art would have to perform a large quantity of unpredictable experimentation to isolate and identify the sequence of the kinase(s) and/or nucleic acid molecule encoding the kinase(s) because neither the art nor the specification teaches a description of the kinase(s), from among the essentially unlimited number of possible polypeptides such that one can make or attempt to isolate for the claimed invention. Such unpredictable experimentation would be undue in the absence of any description of the structures of the claimed kinase(s) and in view of the state of the art, unpredictability in the art, lack of working examples, and lack of guidance.

#### **Conclusion**

No claims are allowed.

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official

Art Unit: 1636

Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is 571-273-8300. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.


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Art Unit: 1636

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Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Terry A. McKelvey whose telephone number is (571) 272-0775. The examiner can normally be reached on Monday through Friday, except for Wednesdays, from about 7:30 AM to about 6:00 PM. A phone message left at this number will be responded to as soon as possible (i.e., shortly after the examiner returns to his office).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached at (571) 272-0781.

  
Terry A. McKelvey, Ph.D.  
Primary Examiner  
Art Unit 1636

January 21, 2005